

# 3  
GP/1645

PATENT  
ATTORNEY DOCKET NO. 06132/037002

Certificate of Mailing: Date of Deposit: <u>May 3, 2002</u>	
I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as <b>first class mail</b> with sufficient postage on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.	
<u>Susan M. Barry</u>	<u><i>Susan M. Barry</i></u>
Printed name of person mailing correspondence	Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Harold Kleanthous et al.	Art Unit:	1645
Serial No.:	10/039,183	Examiner:	Not Yet Assigned
Filed:	January 3, 2002	Customer No.:	21559
Title:	Helicobacter GHPO 1360 and GHPO 750 Polypeptides and Corresponding Polynucleotide Molecules		

Assistant Commissioner For Patents  
Washington, DC 20231

RECEIVED  
MAY 10 2002  
TECH CENTER 1600/2900

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the attached form PTO-1449.

Submission of this statement is not a representation that a search has been made, nor is information included in this statement an admission that the information is material to patentability.

Under 35 U.S.C. § 120, this application relies on the earlier filing date of application serial number 08/831,310, filed on April 1, 1997. The following references were submitted to and/or cited by the Office in the prior application and, therefore, copies of these references are not provided in this application:

RECEIVED  
MAY 15 2002  
OIP/CCMS

5,116,821	05/26/92	Randall et al.
5,128,140	07/07/92	Chapura et al.
5,258,178	11/02/93	Cordle et al.
5,447,923	09/05/95	Catrenich et al.
5,476,669	12/19/95	Borody
5,514,660	05/07/96	Zopf et al.
5,538,729	07/23/96	Czinn et al.
5,563,039	10/08/96	Goeddel et al.
5,567,594	10/22/96	Calenoff
5,610,060	03/11/97	Ward et al.
5,620,964	04/15/97	Roth et al.
5,679,769	10/21/97	Danishefsky et al.
5,753,630	05/19/98	Zopf et al.
WO 91/09049	27.06.91	PCT
WO 93/18150	16.09.93	PCT
WO 94/09823	11.05.94	PCT
WO 95/22987	31.08.95	PCT
WO 95/33482	14.12.95	PCT
WO 96/33732	31.10.96	PCT
WO 96/38475	05.12.96	PCT
WO 96/40893	19.12.96	PCT
WO 97/03359	30.01.97	PCT

WO 97/03360 30.01.97	PCT
WO 97/19098 29.05.97	PCT
WO 97/11182 27.03.97	PCT
WO 97/12908 10.04.97	PCT
WO 97/12909 10.04.97	PCT
WO 97/37044 09.10.97	PCT
WO 98/18323 07.05.98	PCT

Borén et al., "Attachment of *Helicobacter pylori* to Human Gastric Epithelium Mediated by Blood Group Antigens," Science 262:1892-1895 (1993).

Borody et al., "Omeprazole Enhances Efficacy of Triple Therapy in Eradicating *Helicobacter pylori*," Gut 37:477-481 (1995).

Clayton et al., "Sensitive Detection of *Helicobacter pylori* by Using Polymerase Chain Reaction," Journal of Clinical Microbiology 30:192-200 (1992).

Czinn et al., "Oral Immunization Against *Helicobacter Pylori*," Infection and Immunity 59:2359-2363, 1991.

Doig et al., "Identification of Surface-Exposed Outer Membrane Antigens of *Helicobacter pylori*," Infection and Immunity 62:4526-4533 (1994).

Drouet et al., "Partial Characterization of an External Polysaccharide of *Helicobacter pylori* by Using an Immunoglobulin M Monoclonal Antibody," Infection and Immunity 61:2732-2736 (1993).

Fauchere et al., "Adherence of *Helicobacter pylori* Cells and Their Surface Components to HeLa Cell Membranes," Microbial Pathogenesis 9:427-439 (1990).

Ferrero et al., "Recombinant Antigens Prepared from the Urease Subunits of *Helicobacter* spp.: Evidence of Protection in a Mouse Model of Gastric Infection," Infection and Immunity 62:4981-4989 (1994).

Graham et al., "Effect of Triple Therapy (Antibiotics plus Bismuth) on Duodenal Ulcer Healing," Annals of Internal Medicine 115:266-269 (1991).

Haas et al., "TnMax- a Versatile Mini-Transposon for the Analysis of Cloned Genes and Shuttle Mutagenesis," *Gene* 130:23-31 (1993).

Husson et al., "Iron Acquisition by *Helicobacter pylori*: Importance of Human Lactoferrin," *Infection and Immunity* 61:2694-2697 (1993).

Illingworth et al., "Siderophore Production and Iron-Regulated Envelope Proteins of *Helicobacter pylori*," *Zbl. Bakt.* 280:113-119 (1993).

Kaplan, "Autogenous Vaccination Against *Helicobacter pylori*," *South African Medical Journal* 83:922-923 (1993).

Lee et al., "Oral Immunization with Recombinant *Helicobacter pylori* Urease Induces Secretory IgA Antibodies and Protects Mice from Challenge with *Helicobacter felis*," *The Journal of Infectious Diseases* 172:161-172 (1995).

Mohammadi et al., "*Helicobacter*-Specific Cell-Mediated Immune Responses Display a Predominant Th1 Phenotype and Promote a Delayed-Type Hypersensitivity Response in the Stomachs of Mice," *Journal of Immunology* 156:4729-4738 (1996).

Monath et al., "Development of Recombinant *Helicobacter pylori* Urease as an Oral Vaccine: Current Status," *Gut* 37(Supp 1):A52 (1995).

Myers et al., "Oral Immunization with Recombinant Urease Confers Long-Lasting Immunity," *Gut* 39(Supp 2):A94 (1996).

Nakao et al., "Antibacterial Properties of Lansoprazole Alone and in Combination with Antimicrobial Agents against *Helicobacter pylori*," *Eur. J. Clin. Microbiol. Infect. Dis.* 14:391-399 (1995).

Robinson et al., "Protection against a Lethal Influenza Virus Challenge by Immunization with a Haemagglutinin-Expressing Plasmid DNA," *Vaccine* 11:957-960 (1993).

Robinson et al., "Use of Direct DNA Inoculations to Elicit Protective Immune Responses," *Vaccine* 93, Cold Spring Harbor Laboratory Press, 311-315 (1993).

Sherburne et al., "*Helicobacter pylori* Expresses a Complex Surface Carbohydrate, Lewis X," *Infection and Immunity* 63:4564-4568 (1995).

Thijs et al., "Efficacy and Side Effects of a Triple Drug Regimen for the Eradication of *Helicobacter pylori*," *Scand. J. Gastroenterol.* 28:934-938 (1993).

Tomb et al., "The Complete Genome Sequence of the Gastric Pathogen *Helicobacter pylori*," *Nature* 388:539-547 (1997).

Ulmer et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," Science 259:1745-1749 (1993).

Wadstrom, "Microbial Adhesion: New Concepts for Development of Antiadhesion Strategies to Combat Bacterial Infections," Acta Microbiological Hungarica 38:164-165 (1991).

Lee et al., U.S. Serial No. 08/568,122, filed December 6, 1995.

Haas et al., U.S. Serial No. 10/013,315, filed November 5, 2001.

Kleanthous et al., U.S. Serial No. 08/834,666, filed April 1, 1997.

Haas et al., U.S. Serial No. 08/834,705, filed April 1, 1997.

Haas et al., U.S. Serial No. 09/988,067, filed November 16, 2001.

Kleanthous et al., U.S. Serial No. 09/881,752, filed June 15, 2001.

Kleanthous et al., U.S. Serial No. 09/895,913, filed June 29, 2001.

If there are any other charges or any credits, please apply them to Deposit Account  
No.03-2095.

Respectfully submitted,

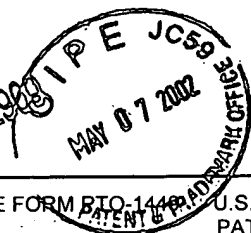
Date: May 3, 2002

Susan M. Michaud  
Susan M. Michaud, Ph.D.  
Reg. No. 42,885

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045  
06132.037002 Information Disclosure Statement.wpd



RECEIVED  
MAY 10 2002  
TECH CENTER 1600/2003



Sheet 1 of 5

SUBSTITUTE FORM PTO-1449  
(MODIFIED)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
(Use several sheets if necessary)

(37 CFR §1.98(b))

Attorney Docket No.	06132/037002
Serial No.	10/039,183
Applicant	Kleanthous et al.
Filing Date	January 3, 2002
Group	Not Yet Assigned
IDS Filed	May 3, 2002
Customer No.	21559

U.S. PATENTS

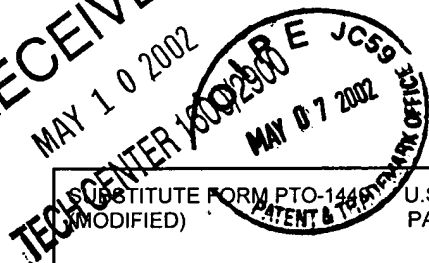
Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
	5,116,821	05/26/92	Randall et al.			
	5,128,140	07/07/92	Chapura et al.			
	5,258,178	11/02/93	Cordle et al.			
	5,447,923	09/05/95	Catrenich et al.			
	5,476,669	12/19/95	Borody			
	5,514,660	05/07/96	Zopf et al.			
	5,538,729	07/23/96	Czinn et al.			
	5,563,039	10/08/96	Goeddel et al.			
	5,567,594	10/22/96	Calenoff			
	5,610,060	03/11/97	Ward et al.			
	5,620,964	04/15/97	Roth et al.			
	5,679,769	10/21/97	Danishefsky et al.			
	5,753,630	05/19/98	Zopf et al.			
	5,837,240	11/17/98	Lee et al.			
	5,972,336	10/26/99	Michetti et al.			
	6,290,962 B1	09/18/01	Michetti et al.			

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

**RECEIVED**  
MAY 10 2002



Sheet 2 of 5

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)  (37 CFR §1.98(b))	Attorney Docket No.	06132/037002
	Serial No.	10/039,183
	Applicant	Kleanthous et al.
	Filing Date	January 3, 2002
	Group	Not Yet Assigned
	IDS Filed	May 3, 2002
Customer No.		21559

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

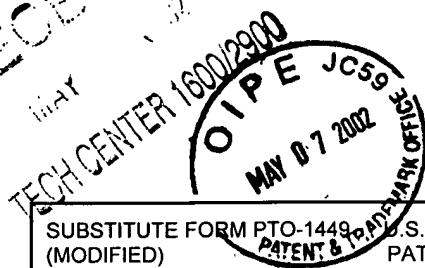
	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
	WO 91/09049	27.06.91	PCT			
	WO 93/18150	16.09.93	PCT			
	WO 94/09823	11.05.94	PCT			
	WO 95/22987	31.08.95	PCT			
	WO 95/33482	14.12.95	PCT			
	WO 96/33732	31.10.96	PCT			
	WO 96/38475	05.12.96	PCT			
	WO 96/40893	19.12.96	PCT			
	WO 97/03359	30.01.97	PCT			
	WO 97/03360	30.01.97	PCT			
	WO 97/19098	29.05.97	PCT			
	WO 97/11182	27.03.97	PCT			
	WO 97/12908	10.04.97	PCT			
	WO 97/12909	10.04.97	PCT			
	WO 97/37044	09.10.97	PCT			
	WO 98/18323	07.05.98	PCT			

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

RECEIVED  
MAY 1 2002

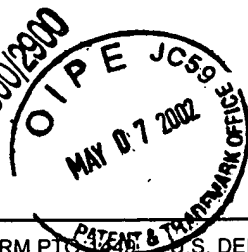


Sheet 3 of 5

SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)  (37 CFR §1.98(b))		Attorney Docket No. 06132/037002 Serial No. 10/039,183 Applicant Kleanthous et al. Filing Date January 3, 2002 Group Not Yet Assigned IDS Filed May 3, 2002 Customer No. 21559
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)		
	Borén et al., "Attachment of <i>Helicobacter pylori</i> to Human Gastric Epithelium Mediated by Blood Group Antigens," <i>Science</i> 262:1892-1895 (1993).	
	Borody et al., "Omeprazole Enhances Efficacy of Triple Therapy in Eradicating <i>Helicobacter pylori</i> ," <i>Gut</i> 37:477-481 (1995).	
	Clayton et al., "Sensitive Detection of <i>Helicobacter pylori</i> by Using Polymerase Chain Reaction," <i>Journal of Clinical Microbiology</i> 30:192-200 (1992).	
	Czinn et al., "Oral Immunization Against <i>Helicobacter Pylori</i> ," <i>Infection and Immunity</i> 59:2359-2363, 1991.	
	Doig et al., "Identification of Surface-Exposed Outer Membrane Antigens of <i>Helicobacter pylori</i> ," <i>Infection and Immunity</i> 62:4526-4533 (1994).	
	Drouet et al., "Partial Characterization of an External Polysaccharide of <i>Helicobacter pylori</i> by Using an Immunoglobulin M Monoclonal Antibody," <i>Infection and Immunity</i> 61:2732-2736 (1993).	
	Fauchere et al., "Adherence of <i>Helicobacter pylori</i> Cells and Their Surface Components to HeLa Cell Membranes," <i>Microbial Pathogenesis</i> 9:427-439 (1990).	
	Ferrero et al., "Recombinant Antigens Prepared from the Urease Subunits of <i>Helicobacter</i> spp.: Evidence of Protection in a Mouse Model of Gastric Infection," <i>Infection and Immunity</i> 62:4981-4989 (1994).	
	Graham et al., "Effect of Triple Therapy (Antibiotics plus Bismuth) on Duodenal Ulcer Healing," <i>Annals of Internal Medicine</i> 115:266-269 (1991).	
	Haas et al., "TnMax- a Versatile Mini-Transposon for the Analysis of Cloned Genes and Shuttle Mutagenesis," <i>Gene</i> 130:23-31 (1993).	
	Husson et al., "Iron Acquisition by <i>Helicobacter pylori</i> : Importance of Human Lactoferrin," <i>Infection and Immunity</i> 61:2694-2697 (1993).	
	Illingworth et al., "Siderophore Production and Iron-Regulated Envelope Proteins of <i>Helicobacter pylori</i> ," <i>Zbl. Bakt.</i> 280:113-119 (1993).	
	Kaplan, "Autogenous Vaccination Against <i>Helicobacter pylori</i> ," <i>South African Medical Journal</i> 83:922-923 (1993).	
	Lee et al., "Oral Immunization with Recombinant <i>Helicobacter pylori</i> Urease Induces Secretory IgA Antibodies and Protects Mice from Challenge with <i>Helicobacter felis</i> ," <i>The Journal of Infectious Diseases</i> 172:161-172 (1995).	
EXAMINER		DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.		



RECEIVED  
MAY 10 2002  
TECH CENTER 1600/200

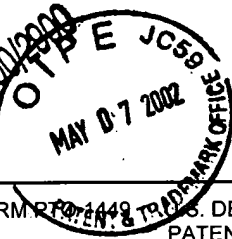


Sheet 4 of 5

SUBSTITUTE FORM PTO 1545 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE		Attorney Docket No. 06132/037002 Serial No. 10/039,183 Applicant Kleanthous et al. Filing Date January 3, 2002 Group Not Yet Assigned IDS Filed May 3, 2002 Customer No. 21559
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR §1.98(b))		
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)		
	Mohammadi et al., " <i>Helicobacter</i> -Specific Cell-Mediated Immune Responses Display a Predominant Th1 Phenotype and Promote a Delayed-Type Hypersensitivity Response in the Stomachs of Mice," Journal of Immunology 156:4729-4738 (1996).	
	Monath et al., "Development of Recombinant <i>Helicobacter pylori</i> Urease as an Oral Vaccine: Current Status," Gut 37(Supp 1):A52 (1995).	
	Myers et al., "Oral Immunization with Recombinant Urease Confers Long-Lasting Immunity," Gut 39(Supp 2):A94 (1996).	
	Nakao et al., "Antibacterial Properties of Lansoprazole Alone and in Combination with Antimicrobial Agents against <i>Helicobacter pylori</i> ," Eur. J. Clin. Microbiol. Infect. Dis. 14:391-399 (1995).	
	Robinson et al., "Protection against a Lethal Influenza Virus Challenge by Immunization with a Haemagglutinin-Expressing Plasmid DNA," Vaccine 11:957-960 (1993).	
	Robinson et al., "Use of Direct DNA Inoculations to Elicit Protective Immune Responses," Vaccine 93, Cold Spring Harbor Laboratory Press, 311-315 (1993).	
	Sherburne et al., " <i>Helicobacter pylori</i> Expresses a Complex Surface Carbohydrate, Lewis X," Infection and Immunity 63:4564-4568 (1995).	
	Thijs et al., "Efficacy and Side Effects of a Triple Drug Regimen for the Eradication of <i>Helicobacter pylori</i> ," Scand. J. Gastroenterol. 28:934-938 (1993).	
	Tomb et al., "The Complete Genome Sequence of the Gastric Pathogen <i>Helicobacter pylori</i> ," Nature 388:539-547 (1997).	
	Ulmer et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," Science 259:1745-1749 (1993).	
	Wadstrom, "Microbial Adhesion: New Concepts for Development of Antiadhesion Strategies to Combat Bacterial Infections," Acta Microbiologica Hungarica 38:164-165 (1991).	
EXAMINER		DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.		

RECEIVED  
MAY 10 2002

TECH CENTER 16000000



Sheet 5 of 5

SUBSTITUTE FORM PTO-1449 (MODIFIED)  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)  (37 C.F.R. §1.98(b))	Attorney Docket No.	06132/037002
	Serial No.	10/039,183
	Applicant	Kleanthous et al.
	Filing Date	January 3, 2002
	Group	Not Yet Assigned
	IDS Filed	May 3, 2002
Customer No.	21559	

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

	Lee et al., U.S. Serial No. 08/568,122, filed December 6, 1995.
	Haas et al., U.S. Serial No. 10/013,315, filed November 5, 2001.
	Kleanthous et al., U.S. Serial No. 08/834,666, filed April 1, 1997.
	Haas et al., U.S. Serial No. 08/834,705, filed April 1, 1997.
	Haas et al., U.S. Serial No. 09/988,067, filed November 16, 2001.
	Kleanthous et al., U.S. Serial No. 09/881,752, filed June 15, 2001.
	Kleanthous et al., U.S. Serial No. 09/895,913, filed June 29, 2001.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.